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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,040	07/24/2003	Michael Lebner	0156-2008US01	1249
7590 Kevin M. Farrell Suite 350 One New Hampshire Avenue Portsmouth, NH 03801			EXAMINER LEWIS, KIM M	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 08/21/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/626,040	Applicant(s) LEBNER, MICHAEL	
	Examiner Kim M. Lewis	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/28/08.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-20 and 23-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-20 and 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/28/08 has been entered.
2. As requested in the submission, claims 1 and 20 have been amended. Claims 1, 4-20 and 23-38 are pending in the instant application.

Specification

3. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0193216 ("Deutsch") in view of U.S. Patent No. 5, 176, 703 ("Peterson").

7. As regards claim 1, Deutsch substantially discloses all features of the claim including a two component device for closing a wound or lacerations comprising, a first adhesive backed anchoring member (18a) , one or more first connecting members (20) attached to the adhesive backed anchoring member, a second adhesive backed anchoring member (18b), one or more second connecting members (20) attached to the adhesive backed anchoring member, and hook and loop means(an equivalent for adhesive) for attaching the one or more first connecting members to the second adhesive backed anchoring member and hook and loop attaching means (an equivalent of adhesive) for attaching the one or more second connecting members to the first adhesive backed anchoring member.

Deutsch fails to teach the first and second adhesive backed anchoring members (18a, 18b) are constructed from elastic material and further fails to teach that the one or

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more first and second connected members are constructed from substantially inelastic material. Peterson, however, discloses a wound or incision closure device comprising first and second adhesive backed anchoring members (20, 22; cl. 3, lines 1-12) constructed from elastic material and one or more first and second connected members constructed from substantially inelastic material (cl. 3, lines 31-34), for the obvious and inherent purpose of allowing the tape to contour the skin and to prevent movement/stretching of the connecting members when placed on the user so as to prevent unwanted movement of the incision.

8. Claims 4, 6, 10-12, 18-20, 23, 25, 29-31, 33, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deutsch in view of Peterson as applied to claim 1 above, and in further view of U.S. Patent No. 6,329,564 ("Lebner").

As regards claims 4 and 6, Deutsch fails to teach pulling elements and that extensions of connecting members are removable. Lebner, however, discloses an incision closure device comprising pulling elements (40, 45) and extensions of the connecting members that are removable at perforations (17, 37) following application of the device. The applicant should note that the extension of the connecting members is defined as the portion of the connecting member severed with pulling elements (40, 45).

It would have been obvious to one having ordinary skill in the art to provide the modified device of Deutsch with pulling elements and removable extensions in order to easily apply the wound closure device with minimal contact of the adhering portions to

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the hand and thereby minimizing the spread of bacteria from the hands to the incision site.

Regarding claim 10, Deutsch and Peterson are silent as to a vapor permeable material. Lebner, however, discloses a device that is constructed from a vapor-permeable in order to allow for the exchange of air (col. 3, lines 5-15). In view of Lebner, it would have been obvious to one having ordinary skill in the art to construct the two-component device of Deutsch from vapor permeable material in order to allow for the exchange of air.

Regarding claims 11, 12 and 14, Deutsch discloses hook and loop material as the means. Lebner, however, discloses at col. 1, lines 43-46 and col. 1, line 66-col. 2, line 2, adhesive means for attaching the connecting members to the anchoring member and respective release liners for their protection (col. 1, lines 48-65). It would have been obvious to one having ordinary skill in the art to substitute the hook and loop attaching means of Deutsch for the adhesive attaching means of Lebner since they both perform the same function of adhering the connecting members to the anchoring members. It would have further obvious to include the release sheets to protect the adhesive and members prior to use.

As regards claims 18 and 19, the modified device of Deutsch fails to teach reinforcements. Lebner, however, teaches the use of reinforcements at col. 2, lines 60-col. 3, line 4 for the purpose of strengthening the edge of the device and the pulling element. Thus, it would have been obvious to one having ordinary skill in the art to add reinforcements of the pulling element and anchoring members to strengthen the device

Regarding claim 20, mere use of the modified device of discussed above in the rejection of claim 1 above obviates the claimed invention. The applicant should note that manipulating the pulling elements for attachment onto the anchoring member such that the wound or laceration is closed, necessarily involves adjusting the position of anchoring members in both an x and y dimension.

Regarding claims 23, 25, 29-31, 33, 37 and 38, note the rejection of claims 4, 6, 10-12, 14, 18 and 19, respectively.

Regarding claims 5 and 7-9, Lebner fails to teach that the pulling elements are coded to enable user distinction, that the coding comprises an observable geometric distinction between the shape of the pulling elements and the shape of the anchoring members, that the coding comprises printed indicia enabling user distinction between pulling elements and anchoring members, that the coding on the pulling elements distinguishing colors, or that the anchoring members are provided with one or more alignment indicators. However, Lebner discloses at col. 4, lines 38-53, that the bandage can include wound closure visual alignment indicators, and further discloses at col. 5, lines 1-21, that the bandage can include indicia (e.g., color, graphic representations, etc.) for the purpose of indicating specific information to the user (e.g., tension). In light of these disclosures, it would have been prima facie obvious to one having ordinary skill in that art at the time of invention to provide any portion of the Lebner bandage with indicia of various types (e.g., colors, shapes, printed material, etc.) in order to indicate any information.

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Regarding claims 13 and 15-17, note the rejection of claims 5 and 7-9 above.

The same rationale applies to claims 13 and 15-17. As such, the claims are not distinguishable over the prior art.

Regarding claims 24, 26-28, 32, and 34-36, note the rejection of claims 5, 7-9, 10, 13 and 15-17 above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/

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Primary Examiner
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kml
August 17, 2008